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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,699	12/09/2003	Darren A. Janzig	1023-331US01	3259
28863 7590 10/25/2007 SHUMAKER & SIEFFERT, P. A. 1625 RADIO DRIVE SUITE 300 WOODBURY, MN 55125			EXAMINER MANUEL, GEORGE C	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/731,699	Applicant(s) JANZIG ET AL.	
	Examiner George Manuel	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-15 and 17-25 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-15, 17-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/16/07</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 25 stands rejected under 35 U.S.C. §102(b) as being anticipated by Lynch (US 4,934,368). Lynch is considered to disclose:

- a first module comprising implant case 12, and
- a second module comprising nerve cuff 2, and
- a coupling module comprising lead 3.

The coupling module (lead 3) is inherently hermetically sealed to both housing using silicone rubber.

Claims 7-11, 14, 15, 17 and 20-23 stand rejected under 35 U.S.C. §102(b) as being anticipated by Hirschberg et al (US 5,312,440). Hirschberg et al is considered to disclose:

- a first module comprising housing 15, and
- a second module comprising implantable defibrillator 1, and
- a coupling module comprising lead 9.

Lead 9, terminals 7 and 16 are inherently hermetically fixed to the first and second housing to prevent bodily fluids from entering and shorting the electrical connections.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-6 and 24 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Lynch (US 4,934,368).

Lynch discloses all of the claimed features except for an overmold that at least partially encapsulates each of the housings and a thickness of between approximately 4 millimeters and approximately 8 millimeters.

Lynch teaches the point where the lead 3 enters the case 12, a layer of silicone rubber 25 is applied to absorb lateral strain on the lead. Further, the cuff 2 may either be formed integrally with the lead 3 or formed separately and sealed to the lead 3 by a dip coat of silicone rubber.

One of ordinary skill in the art would have found it obvious to coat both the case 12 and the lead 3 with a dip coating of silicone because Lynch teaches the layer of soft silicone 25 is applied after the lead and case have been assembled and because a dip coating is also an after an assembly process.

Claims 12, 13, 18 and 19 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Hirschberg et al (US 5,312,440).

Hirschberg et al disclose all of the claimed features except for a hermetically fixed attachment, a weld joint, or a bellows section.

One of ordinary skill in the art would have found it obvious to weld the titanium to make a hermitic seal to prevent corrosion and seal out bodily fluids. A bellows would be an obvious addition to permit axial flexibility to permit easier use of the housing 15.

Hirschberg et al provide motivation by teaching the structure of the housing can be altered dependent on the implantation location in the body of the patient.

Regarding claim 19, one of ordinary skill in the art would have found it obvious to include a third module because Hirschberg et al teach the illustrated selection and arrangement of the components in housing 15 are considered only as examples and that a plurality of further possible combinations are within the scope of disclosed invention. A third module would be within the scope of expected possible combinations.

Claims 7, 8, 19 and 25 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Meltzer (US 5,645,586).

Meltzer shows all of the claimed features except for a coupling module that defines at least one lumen between the first and second housings. One of ordinary skill in the art would have found it obvious to modify the device of Meltzer to include a coupling module that defines at least one lumen between the first and second housings because Meltzer teaches the number of housing segments, as well as the manner in which the housing segments are joined for pivotal movement, may take many forms, depending upon the application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

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1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of US Pat. No. 7,212,864. The two modules of the claimed application possess an identical housing to that of the copending application. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to provide an implantable medical device for implantation in the head of a patient with variations of a first and second module including a flexible overmold to cover the modules.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Response to Arguments

Applicant's arguments filed 8/16/07 have been fully considered but they are not persuasive. Lynch discloses a lead 3 that defines a tubular passage (lumen) with conductive wire inside the passage. Applicant's suggestion that support is lacking for the lead 3 to be inherently hermetically sealed to both housing with silicone rubber is

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negated by an overall reading of the Lynch reference. For example, Lynch discloses, "[a]t the point where the leads 3 enter the case 12, a layer of soft silicone rubber 25 is applied to absorb any lateral strain on the leads 3. This layer of soft silicone 25 is applied after the case 12 and leads 3 have been assembled and can be removed, for example, by cutting, if a lead 3 needs to be replaced."


Applicant's arguments with respect to claims 7-15 and 17-23 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Manuel whose telephone number is (571) 272-4952.


George Manuel
Primary Examiner
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